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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,580	11/21/2003	Frederic Beseme	105045.01	3397

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EXAMINER

MCGILLEM, LAURA L

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,580	Applicant(s) BESEME ET AL.	
	Examiner Laura McGillem	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 11, 18, 19, 21-24 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-17, 20, 25-27 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group (11) Eleven in the reply filed on 10/24/2005 is acknowledged. The traversal is on the ground(s) that the subject matter of all claims 1-35 is sufficiently related that a thorough search for the subject matter of any one Group of claims would encompass a search for the subject matter of the remaining claims without serious burden. This is not found persuasive because the claimed invention encompasses 15 separate nucleotide sequences. According to the policy for the examination of patent applications that claim large numbers of nucleotide sequences (see MPEP 2434), up to 10 independent and distinct nucleotide sequences will be examined in a single application wherein "up to 10" can mean only one nucleotide sequence. Claims 11, 18-19, 21-24, 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/24/2005. The requirement is still deemed proper and is therefore made FINAL. Claims 1-10, 12-17, 20, 25-27 and 31-35 are pending.

Priority

The instant application is a CONTINUATION of Patent Application No. 09/446,024, now abandoned. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 07/07/1997. It is noted, however, that

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applicant has not filed a certified copy of the 97/08815 application as required by 35 U.S.C. 119(b). Therefore, this Application receives priority to PCT/FR98/01442, filed 07/06/1998.

Specification

The Brief Description of Drawings is objected to because Figure 4 contains multiple panels labeled A, B and C, and Figure 5 contains two panels labeled A and B, but the individual panels are not identified or described in the Specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4, 7, 12, 31-32 and 34-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to nucleic material or nucleotide fragments. Because said nucleic material or nucleotide fragments are not recited as isolated or recombinant, they read on products of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-6, 8-10, 13-17, 20, 25-27 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite because it recites a nucleic acid sequence identical to SEQ ID NO: 11, with at least one deletion and it is not clear whether the nucleic acid sequence can contain at least one deletion and is otherwise identical to SEQ ID NO: 11 in order to meet the limitations of the claim, or if SEQ ID NO:11 has at least one deletion and the nucleic sequence is identical to SEQ ID NO:11 containing at least one deletion.

Claims 1-6, 8, 10, 20, 25-27 and 31-32 are vague and indefinite because they recite the phrase "nucleic material" and it is not clear what is meant by a "nucleic material", as this is not a term commonly used in the art.

Claims 8 and 13-17 are vague and indefinite because they recite the phrase "nucleic probe" and it is not clear what is meant by nucleic probe.

Claims 8 and 9 are vague and indefinite because they recite "highly stringent conditions" and the metes and bounds of "highly stringent" are not clear. The instant specification does not define highly stringent conditions.

Claim 10 is vague and indefinite because it recites the phrase "amplification by polymerization of an RNA or DNA" and it is not clear how merely polymerizing RNA or DNA would amplify.

Claim 26 is vague and indefinite because it recites that a peptide sequence is "capable of being encoded" and is not clear what is meant by "capable of being encoded".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 12 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,582,703.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants claim a nucleotide fragment comprising an equivalent nucleotide sequence which has at least 50% or at least 70% homology to a nucleotide sequence of at least 100 bases of HERV-W (SEQ ID NO: 11) and complementary sequences thereof

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Patent '703 teaches a nucleotide sequence identified as SEQ ID NO:87 which corresponds to the pol gene of a retrovirus (see column 4, lines 56-58, for example). The attached Sequence Identity search demonstrates that a sequence taught by Patent '703 identified as SEQ ID NO: 87 (2304 bp) has 87.2% local sequence identity with bases 2025-4351 of SEQ ID NO:11. Nucleotides 1-118 of SEQ ID NO: 87 correspond with a fragment of instant SEQ ID NO: 11 from nt 2025 to nt 2141 with 13 mismatches which equates to ~88.9 percent homology, which reads on an RNA or DNA comprising a nucleotide fragment comprising an equivalent nucleotide sequence which has at least 50% homology and at least 70% homology to a nucleotide sequence of at least 100 bases of HERV-W (SEQ ID NO: 11) and the complementary sequence. Patent '703 teaches a replication vector comprising a genomic viral fragment such as SEQ ID NO:87 (see column 7, lines 65-67 and column 4, lines 56-59, for example), which reads on a replication vector comprising a nucleotide fragment with at least 50% homology to a fragment of at least 100 bases of SEQ ID NO:11.

Claims 7, 12 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,001,987.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the

reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The attached Sequence Identity search demonstrates that a sequence taught by Patent '987 identified as SEQ ID NO: 57 (2391 bp) has ~78.4% local sequence identity with bases 2021-2235 of SEQ ID NO:11. Nucleotides 1-120 of SEQ ID NO: 57 correspond with a fragment of instant SEQ ID NO: 11 from nt 2021 to nt 2137 with 11 mismatches which equates to ~89 percent homology, which reads on a nucleotide fragment comprising an equivalent nucleotide sequence which has at least 50% and at least 70% homology to a nucleotide sequence of at least 100 bases of HERV-W (SEQ ID NO: 11) and the complementary sequence. Patent '987 teaches that the nucleotide sequence identified as SEQ ID NO:57 corresponds to the pol gene of a retrovirus (see column 4, lines 4-7, for example), reads on an RNA or DNA comprising a nucleotide fragment comprising an equivalent nucleotide sequence which has at least 50% homology to a nucleotide sequence of at least 100 bases of SEQ ID NO: 11. Patent '987 teaches a replication vector comprising a genomic viral fragment such as SEQ ID NO:57 (see column 5, lines 39-43 and column 4, lines 4-7, for example), which reads on a replication vector comprising a nucleotide fragment with at least 50% homology to a fragment of at least 100 bases of SEQ ID NO:11.

Claims 7, 12 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Pauley and Waterston, Accession No. AC000064, available to the public since 11/13/1996. Pauley and Waterston submitted the sequence of a human BAC clone

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RG083M05. The attached Sequence identity search (see search report No. 1, result no. 9) reveals an 85% identity with SEQ ID NO: 11 (nt 606- nt 7582) and a best local similarity of 95.7%. For example, SEQ ID NO: 11 nucleotides 606 to nucleotide 725 aligns with BAC clone RG083M05 nucleotide 91051 to 90932 with only 2 mismatches in a series of 125 nucleotides, which reads on an RNA or DNA comprising a nucleotide fragment comprising an equivalent nucleotide sequence which has at least 50%, at least 70% and at least 90% homology to a nucleotide sequence of at least 100 bases of HERV-W (SEQ ID NO: 11) and the complementary sequence.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
12/6/2005


DAVID GUZO
PRIMARY EXAMINER